REMARKS

Claims 4, 5, 7-19, 22, 24, 27, 28, 30, 33, and 36-60 are pending in the application. Claims 4, 5, 7-19, 22, 24, 27, 28, 30, 33, and 36-60 are rejected. Claims 4, 7, 9, and 17 are presently amended. Claims 8 and 22 are presently cancelled. Claims 61 and 62 are new. Applicant also submits herewith a Declaration of Charles A. Mesko Under 37 C.F.R. 1.132 ("Declaration"). In view of the claim amendments, the Declaration, and the discussion below, Applicant submits that the application is now in condition for allowance.

Status of Claims

On page 2 of the present Office Action, the Examiner states that "claims 4, 30, and 33" have been amended (in the previous response filed January 4, 2008). Applicant notes that claims 8, 13, 17, 24, 27, and 36 were also amended in the response filed January 4, 2008, though those amendments were not substantive, but were made to provide correct dependency of those claims.

Claim Objections

The Examiner has objected to claim 7 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In particular, claim 7 depended from claim 6, which was cancelled in a previous Office Action. In response, Applicant has presently amended claim 7 to depend from claim 4, rather than claim 6. As such, Applicant submits that amended claim 7 is no longer objectionable, and requests a withdrawal of the objection to claim 7.

Claim Rejections 35 U.S.C. § 112

The Examiner has rejected claims 4, 5, 7, 13, 24, 27, 28, and 30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner states that the claimed invention is drawn to a pharmaceutical composition comprising a first ingredient being Eurycoma longifolia jack and a second ingredient effective to stimulate the production of cGMP (these are the limitations of independent claim 4, from which each of claims 5, 7, 13, 24, 27, 28, and 30 ultimately depends). The Examiner suggests that the scope of the claims includes numerous "second ingredients" that are effective to stimulate the production of cGMP, and so the claimed genus is highly variable, and the recitation is therefore insufficient.

In response, Applicant has presently amended independent claim 4 to recite that the second ingredient (which is effective to stimulate the production of cGMP) "is a coumarin." Support for this amendment may be found at least in original claim 8. Further, Applicant notes that original claim 8 (which recited a coumarin as the second ingredient), was not rejected as lacking written description, thereby demonstrating that the Examiner tacitly acknowledges that a claim recitation to the second ingredient being a coumarin has written description support under 35 U.S.C. § 112, first paragraph. In view of the amendment, Applicant respectfully requests a withdrawal of the rejection of claims 4, 5, 7, 13, 24, 27, 28, and 30 under 35 U.S.C. § 112, first paragraph.

The Examiner has also rejected claims 4 and 17 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner states that claims 4 and 17 recite a third ingredient for stimulating an increase in blood flow. The Examiner suggests that the scope of the

claims includes numerous "third ingredients" that are effective to stimulate such an increase in blood flow, and so the claimed genus is highly variable, and the recitation is therefore insufficient.

As an initial matter, Applicant notes that claim 4 does not include any recitation to a "third ingredient," and so submits that the Examiner's rejection of claim 4 for this reason is in error, and requests withdrawal of same.

Further, in response, Applicant has presently amended claim 17 to recite that the third ingredient is "provided in homeopathic form." Support for this amendment may be found at least in originally filed claim 22. Further, Applicant notes that original claim 22 (which recited the homeopathic form), was not rejected as lacking written description, thereby demonstrating that the Examiner tacitly acknowledges that a claim recitation to the third ingredient being provided in homeopathic form has written description support under 35 U.S.C. § 112, first paragraph. In view of the amendment, Applicant respectfully requests a withdrawal of the rejection of claim 17 under 35 U.S.C. § 112, first paragraph.

The Examiner has also rejected claim 7 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner notes that claim 7 depends on claim 6, which is a cancelled claim. As described above in the "Claim Objections" section, Applicant has presently amended claim 7 to be dependent from claim 4 rather than claim 6. Applicant therefore respectfully requests a withdrawal of the rejection of claim 7 under 35 U.S.C. § 112, second paragraph.

Claim Rejections 35 U.S.C. § 103

Garfield/Ang/Chwalisz/Coral-Cure/Chen/Chiou

The Examiner has rejected claims 4, 5, 7-19, 22, 24, 27, 28, 30, 33, and 36 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,595,970 (Garfield) taken with Ang et al. Arch Pharm Res. 2001, 24(5):437-40, 2001, Abstract (Ang) and U.S. Patent No. 5,906,987 (Chwalisz), and Coral-Cure, www.coral-cure.com/mens-health (Coral-Cure) in view of Chen et al. Exp. Opin. Ther. Patents (Chen), Bulk Nutrition 1, 2002 (Bulk Nutrition), and Chiou et al. Planta Med. 2001 67:282-284 (Chiou). Applicant respectfully disagrees.

The claims rejected by the Examiner as obvious over Garfield taken with Ang, Chwalisz, and Coral-Cure, in view of Chen, Bulk Nutrition, and Chiou include independent claims 4 and 33 (claims 5, 7-19, 22, 24, 27, 28, 30, and 36 are ultimately dependent on either claim 4 or claim 33). Regarding independent claim 4, the Examiner states that Garfield teaches a second ingredient to stimulate the production of cyclic GMP, but does not teach Eurycoma longifolia jack. However, the Examiner states that Ang teaches that Eurycoma longifolia jack "has gained notoriety of a symbol of a man's ego when administered." Thus, the Examiner suggests that a person of ordinary skill in the art would be motivated to add the natural herb (i.e., Eurycoma longifolia jack) taught by Ang to the composition of Garfield, since Eurycoma longifolia jack has the same function as testosterone. Applicant respectfully disagrees.

In particular, Applicant submits that Garfield teaches away from Ang such that any addition of Eurycoma longifolia jack (from Ang) to the composition of Garfield is

unnecessary, due to the presence of other ingredients in the composition of Garfield. At least at column 3, lines 58-64, Garfield teaches a composition of a nitric oxide donor alone, a nitric oxide donor combined with a progestin, or a nitric oxide donor and progestin combined with an androgen, when used in males. Thus, Garfield already teaches a composition that includes an androgen. As is known to those of ordinary skill in the art, an androgen is a compound that stimulates, affects, or controls the development of masculine characteristics by binding to androgen receptors. The most commonly known and primary androgen is testosterone. Thus, since the composition of Garfield already includes an androgen (e.g., testosterone), one skilled in the art would not look to Ang or any other reference to add Eurycoma longifolia jack to Garfield's composition, since the function of Eurycoma longifolia jack is to potentiate testosterone. In other words, since the composition of Garfield already includes androgens, such as testosterone, there would be no need to add further androgens, such as testosterone, or an ingredient that potentiates testosterone. Garfield itself thus counsels away from looking to other references for androgens or compounds that potentiate androgens. In view of the above, Applicant respectfully requests a withdrawal of the rejection of independent claim 4 as obvious over Garfield taken with Ang, Chwalisz, and Coral-Cure in view of Chen, Bulk Nutrition, and Chiou under 35 U.S.C. § 103. As independent claim 4 is nonobvious, Applicant further requests a withdrawal of the rejection of dependent claims 5, 7-19, 22, 24, 27, 28, and 30 (as each of those claims ultimately depends from independent claim 4) as obvious under 35 U.S.C. § 103.

Regarding independent claim 33, the Examiner states that Chiou teaches the vasorelaxing effects of coumarins from Cnidium monnier. Chiou does not teach a vesicle operable for transporting the first ingredient including a coumarin. However, the Examiner states that Chen teaches the use of phosphatidyl choline as a vesicle carrier. The Examiner therefore suggests that a person of ordinary skill in the art would be motivated to deliver the Cnidium monnier of Chiou via the vesicle of Chen because phosphatidyl choline is a major component of cellular membranes, and functions in the transport of lipoproteins into tissues. Applicant respectfully disagrees and submits that a composition including a coumarin and a vesicle for transdermal delivery would not be obvious in view of Chiou and Chen. In particular, Applicant asserts that the knowledge of those of ordinary skill in the art regarding coumarins (such as those described in Chiou) teaches away from transdermal delivery via vesicles (such as those described in Chen).

Chiou is a study of the effects of four known coumarins (osthole, imperatorin, xanthotoxin, and isopimpinellin) on penile erectile tissue. The effects of these coumarins were tested by excising the corpus cavernosum tissue from rabbits, and subjecting the tissue to cumulative additions of the four coumarins, as described at p. 283 of Chiou. However, Chiou does not include any discussion as to how such coumarins would be delivered to a living subject. However, the study of Chiou is related to drugs that are used for the treatment of erectile dysfunction. Existing drugs for erectile dysfunction are generally ingested by the patient, rather than being delivered by other means (e.g., transdermally, parenterally, etc.) (see Declaration, para. 9). Thus,

the study of Chiou would be used in preparing drugs or compositions including coumarins that would be delivered via ingestion by a subject (see Declaration, para. 9).

And there are reasons why compositions including coumarins would be delivered via ingestion, and why those of ordinary skill in the art would not transdermally deliver compositions including coumarins. Coumarins include chemical compounds that are toxins, and are moderately toxic to the liver and kidneys (see Declaration, para. 10). In fact, coumarins have been banned as a food additive in numerous countries since the mid-20th century because of the clinical demonstration of coumarins being moderately toxic to both the liver and kidneys (see Declaration, para. 10). European health agencies have warned against consuming high amounts of cassia bark, one of the four species of common cinnamon, because of its coumarin content (see Declaration, para. 10). And, coumarin was banned as a food additive in the United States in 1978, and is currently listed by the United States Food and Drug Administration among "Substances Generally Prohibited from Direct Addition or Use as Human Food" (see Declaration, para. 10).

However, in smaller amounts, humans can metabolize coumarins, and certain studies have established tolerable daily intakes of coumarins when ingested, because they are subjected to processing by the human system, including the liver (see Declaration, para. 11). As is known to those of ordinary skill in the art, the liver plays a major role in metabolism, and has a number of functions in the body, including detoxification of substances that are ingested (known as the "first-pass effect") (see Declaration, para. 11). The first-pass effect is part of drug metabolism whereby the

concentration of a drug is reduced before it reaches the circulatory system. In particular, as is known to those of ordinary skill in the art, after a drug is swallowed, it is absorbed by the digestive system and is carried into the liver before it reaches the rest of the body (see Declaration, para. 11). The liver metabolizes the drug, sometimes such that only a small amount of active drug emerges from the liver to the circulatory system (see Declaration, para. 11). This first-pass effect reduces the toxicity of coumarins (see Declaration, para. 11).

However, transdermal delivery (e.g., through the use of liposomes), avoids the first-pass effect because it allows the composition to be absorbed directly into the bloodstream. In fact, Chen (at p.1035) specifically states that "[t]he use of a transdermal drug delivery system can avoid first pass hepatic or intestinal metabolism . . ." As a result, while one of ordinary skill in the art would deliver a composition including coumarins via ingestion, they would not deliver such a composition transdermally via a vesicle [because they would consider that bypassing the liver (by using a liposome) would allow the coumarins to retain toxicity] (see Declaration, para. 12). Thus, a person of ordinary skill in the art would not think to deliver a coumarin in a transdermal manner, and thus would not prepare or provide a transdermal composition including a coumarin (as claimed in the '417 Application) (see Declaration, para. 12). Thus, the present invention is a complete change in direction from that known by those of ordinary skill in the art, and taught in the cited art.

Garfield/Ang/Chwalisz/Coral-Cure/Chen/Bulk Nutrition/Chiou/Mesko/McKoy

The Examiner has also rejected claims 37-60 as obvious over Garfield taken with Ang, Chwalisz, and Coral-Cure, in view of Chen, Bulk Nutrition, and Chiou in further view of U.S. Patent No. 6,340,474 (Mesko) and McKoy et al. Proc. West. Pharmacol. Soc., 45:76-78 2002 (McKoy). Applicant respectfully disagrees.

Independent claim 37 (from which each of claims 38-60 ultimately depend) recites a composition including (1) "a first ingredient chosen from a hormone, a composition which potentiates a hormone, and mixtures thereof," and (2) "a second ingredient chosen from Morinda citrifolia and an extract of Morinda citrifolia." The Examiner previously pointed to Garfield as teaching a hormone, and points to McKoy as teaching that Morinda citrifolia is used to treat sexual dysfunction. The Examiner then states that since it is known in the art that Morinda citrifolia is used to treat sexual dysfunction, one of ordinary skill in the art would add that ingredient (presumably to the composition of Garfield – though the Examiner never specifically states that) to enhance the overall activity of the composition when administered for the same treatment. Applicant disagrees.

In particular, Applicant submits that Garfield teaches away from McKoy such that any addition of Morinda citrifolia (from McKoy) to the composition of Garfield is unnecessary, due to the presence of other ingredients in the composition of Garfield. At least at column 3, lines 58-64, Garfield teaches a composition of a nitric oxide donor alone, a nitric oxide donor combined with a progestin, or a nitric oxide donor and progestin combined with an androgen, when used in males. Thus, Garfield already teaches a composition that includes an androgen. As is known to those of ordinary skill

in the art, an androgen is a compound that stimulates, affects, or controls the development of masculine characteristics by binding to androgen receptors. The most commonly known and primary androgen is testosterone. Thus, since the composition of Garfield already includes an androgen (e.g., testosterone), one skilled in the art would not look to McKoy or any other reference to add Morinda citrifolia to Garfield's composition, since the function of Morinda citrifolia is to mimic certain effects of increased levels of testosterone (thereby reducing sexual dysfunction). In other words, since the composition of Garfield already includes androgens, such as testosterone, (which alleviate sexual dysfunction) there would be no need to add further ingredient that alleviates sexual dysfunction. Garfield itself thus counsels away from looking to other references for ingredients that do what the composition of Garfield already does.

In view of the above, Applicant respectfully requests a withdrawal of the rejection of independent claim 37 as obvious under 35 U.S.C. § 103(b). As independent claim 37 is nonobvious, Applicant further requests the withdrawal of the rejection of dependent claims 38-60 (as each of those claims ultimately depends from independent claim 37) as obvious under 35 U.S.C. § 103(b).

Conclusion

For the foregoing reasons, it is submitted that all claims are patentable, and a Notice of Allowance is respectfully requested.

The Commissioner is authorized to charge Deposit Account No. 23-3000 in the amount of $245.00 for a two-month extension of time under 37 C.F.R.

§ 1.17(a)(1). The Commissioner is authorized to charge Deposit Account No. 23-3000 in the amount of $110.00 for one independent claim in excess of three under 37 C.F.R. § 1.16(h). No other fee is believed due. Any deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,
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